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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,477	04/18/2001	Brendan Larder	07691.0019	8810

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EXAMINER
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CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM-1

<b>Office Action Summary</b>	<b>Application No.</b> 09/836,477	<b>Applicant(s)</b> LARDER ET AL.	
	<b>Examiner</b> Lori A. Clow, Ph.D.	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

**Restriction/Election Requirement**

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I.      Claims 1-27 and 39-42 drawn to a method and computer program of determining a phenotype of a biological sample comprising obtaining a sequence, identifying a mutation, searching a relational database, obtaining a phenotype and determining a phenotype, classified in Class 702, subclass 20;

II.      Claims 28-32, drawn to a method, business method, and computer program for determining a phenotype of a biological sample comprising obtaining a sequence, searching a relational database, obtaining a database phenotype, and determining a phenotype, classified in Class 702, subclass 20.

III.      Claims 33-34, drawn to a method of assessing effectiveness of a therapy on a patient, classified in Class 702, subclass 20.

IV.      Claim 35, drawn to a method of optimizing therapy for a patient, classified in Class 702, subclass 20.

V.      Claim 36, drawn to a method of designing a therapy for a patient, classified in Class 702, subclass 20.

VI.      Claims 37-38, drawn to a business method, classified in Class 705, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions. It is acknowledged that various processing steps may be similar in some cases, however, the designated outcomes for each group are directed to different inventive purposes and there would be undue search burden if all were examined together.

The invention of Group I requires an additional step of identifying a mutation pattern for determining a phenotype, that is not a critical limitation of the invention of Group II.

The inventions of Group I and Group III are unrelated, as the Group III step of assessing effectiveness of a therapy is not included in the invention of Group I.

The inventions of Group I and Group IV are unrelated, as the Group IV step of optimizing therapy is not a limitation in the steps of Group I.

The inventions of Group I and Group V are unrelated, as the Group V step of designing a therapy for a patient is not included in the invention of Group I.

The inventions of Group I and Group VI are unrelated, as Group VI is drawn to a business method, which is not a limitation of Group I.

The inventions of Group II and Group III are unrelated as Group II is drawn to determining a phenotype and the Group III is drawn to assessing the effectiveness of a therapy.

The inventions of Group II and IV are unrelated as Group II is drawn to assessing phenotype and Group IV is drawn to optimizing therapy.

The inventions of Group II and Group V are unrelated as the invention of Group II is drawn to determining phenotype and Group V is drawn to a method of designing a therapy, which include different inventive purposes and outcomes.

The inventions of Group II and Group VI are unrelated. Group VI is drawn to a business method which is not a limitation of Group II (method of determining phenotype).

The inventions of Group III and Group IV are unrelated as Group III is drawn to assessing the effectiveness of a therapy while Group IV is drawn to methods of optimizing a therapy, which do not encompass the same inventive purpose.

The inventions of Group III and Group V are unrelated. Group V includes a method of designing therapy which is not a limitation of Group III.

The inventions of Group III and Group VI are unrelated. Group VI includes a business method which is not a limitation of Group III.

The inventions of Group IV and Group V are unrelated as Group IV is drawn to a method of optimizing therapy while Group V is drawn to a method of designing a therapy which encompasses a different inventive purpose with different outcomes.

The inventions of Group V and Group VI are unrelated. Group VI includes a business method which is not a limitation of the therapy design methods of Group V.

Because these inventions are distinct for the reasons given above and the search required for the various Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

### Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

May 12, 2004  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

*Marjorie A. Moran*  
MARJORIE MORAN  
PATENT EXAMINER